IN THE CLAIMS:

Please amend claims 1, 27, 28, 31 and 34-37 as indicated below.

Please cancel claims 26 and 30 without prejudice.

This listing of claims below will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (Currently Amended) A method of treating a mammal which has impaired glucose tolerance or early stage diabetes mellitus, comprising orally administering ~~an orally~~ a therapeutically effective dose of a pharmaceutical formulation comprising insulin at or shortly before bedtime.

2. (Previously Presented) The method of claim 1 wherein the treating comprises preventing beta cell death or dysfunction.

3. (Previously Presented) The method of claim 1 wherein the treating comprises long term protection from developing overt diabetes.

4. (Previously Presented) The method of claim 1 wherein the treating comprises delaying the onset of overt or insulin dependent diabetes.

5. (Previously Presented) The method of claim 1, wherein the mammal is a rodent, dog, cat, sheep, pig, cow, horse or human.

6. (Original) The method of claim 5, wherein the mammal is a human.

7. (Previously Presented) The method of claim 1, wherein the oral pharmaceutical formulation is administered on a chronic basis.

8. (Previously Presented) The method of claim 1, wherein the oral pharmaceutical formulation is administered nightly for at least two weeks.

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9. (Original) The method of claim 5, which provides a lowering of morning or fasting insulin levels of at least about 20%.

10. (Original) The method of claim 5, which achieves a therapeutically effective reduction in blood glucose after oral administration to a human diabetic patient, and which provides a ratio of portal vein to peripheral blood insulin concentration from about 2.5:1 to about 6:1.

11. (Previously Presented) The method of claim 5, wherein the dose of the pharmaceutical composition is administered through a dosage form that is solid.

12. (Previously Presented) The method of claim 1, wherein the dose of insulin contained in the dosage form is from about 50 Units to about 600 Units (from about 2 to about 23mg).

13. (Previously Presented) The method of claim 1, wherein the dose of unmodified insulin is from about 100 Units (3.8 mg) to about 400 Units (15.3 mg) insulin.

14. (Previously Presented) The method of claim 1, wherein the dose of unmodified insulin is from about 150 Units (5.75 mg) to about 300 Units (11.5 mg).

15. (Previously Presented) The method of claim 1, wherein the dosage form(s) begin delivering insulin into the portal circulation (via absorption through the mucosa of the gastrointestinal tract) to achieve peak levels within about 30 minutes or less.

16. (Original) A method of treating mammals having impaired glucose tolerance or early stage diabetes mellitus, comprising,

orally administering insulin at or shortly before bedtime to mammals having impaired glucose tolerance or early stage diabetes mellitus such that a statistically significant decrease in C-peptide levels from a mean baseline level is achieved in said mammals when said C-peptide level is measured about 8 hours after said oral administration of insulin.

17. (Original) The method of claim 16, wherein said C-peptide levels when measured are decreased by a mean of about 24%.

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18. (Previously Presented) The method of claim 16, wherein plasma insulin levels are reduced by a statistically significant degree from baseline when measured about 8 hours after said oral administration of insulin.

19. (Original) The method of claim 18, wherein said plasma insulin levels are reduced by a mean of about 33% from baseline when measured about 8 hours after said oral administration of insulin.

20. (Previously Presented) The method of claim 16, wherein blood glucose levels are reduced by a statistically insignificant degree from baseline when measured about 8 hours after said oral administration of insulin.

21. (Original) The method of claim 20, wherein said blood glucose levels are reduced by a mean of about 6% from baseline when measured about 8 hours after said oral administration of insulin.

22. (Previously Presented) The method of claim 16, wherein said oral administration of insulin comprises a dose of from about 200 to about 400 units of insulin and an effective amount of a pharmaceutically acceptable delivery agent which facilitates absorption of said insulin from the gastrointestinal tract of said mammals.

23. (Original) The method of claim 22, wherein said pharmaceutically acceptable delivery agent comprises 4-CNAB.

24. (Original) The method of claim 22, wherein said pharmaceutically acceptable delivery agent comprises about 300 mg 4-CNAB.

25. (Previously Presented) The method of claim 16, wherein said insulin is an unmodified insulin.

26. (Canceled)

27. (Currently Amended) ~~A~~ The method of ~~prolonging the effect of an oral administration of an unmodified insulin in order to treat mammals who have impaired glucose tolerance, comprising orally administering at bedtime a dosage form comprising a orally therapeutically effective amount of unmodified insulin to a diabetic patient which~~ claim 1, wherein said orasl

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administration provides an insulin t_{max} at a time point from about 0.1 to about 1.5 hours after said oral administration, such that a statistically significant decrease in C-peptide levels from baseline is achieved in said ~~patients~~ mammal when said C-peptide level is measured about 8 hours after said oral administration of insulin.

28. (Currently Amended) The method of ~~claim 27~~ claim 1, wherein plasma insulin levels are reduced by a statistically significant degree from baseline when measured about 8 hours after said oral administration of insulin.

29. (Previously Presented) The method of claim 1 wherein the treating comprises prophylactically sparing beta cell function.

30. (Canceled)

31. (Currently Amended) The method of ~~claim 30~~ claim 1, wherein said oral administration of insulin comprises a dose of from about ~~200~~ 100 to about 400 units of insulin and an effective amount of a pharmaceutically acceptable delivery agent which facilitates absorption of said insulin from the gastrointestinal tract.

32. (Original) The method of claim 31, wherein said pharmaceutically acceptable delivery agent comprises 4-CNAB.

33. (Original) The method of claim 31, wherein said pharmaceutically acceptable delivery agent comprises about 300 mg 4-CNAB.

34. (Currently Amended) The method of ~~claim 30~~ claim 1, wherein said insulin is an unmodified insulin.

35. (Currently Amended) The method of ~~claim 30~~ claim 1, wherein ~~said~~ C-peptide levels of said mammal are decreased by a mean of about 24% when measured about 8 hours after said oral administration of insulin.

36. (Currently Amended) The method of ~~claim 30~~ claim 1, wherein ~~said~~ plasma insulin levels of said mammal are reduced by a mean of about 33% when measured about 8 hours after said oral administration of insulin.

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37. (Currently Amended) The method of ~~claim 30~~ claim 1, wherein ~~said~~ blood glucose levels of said mammal are reduced by a mean of about 6% when measured about 8 hours after said oral administration of insulin.

38. (Previously Presented) The method of claim 16, wherein said mammal is a human.

39. (Previously Presented) The method of claim 38, wherein said diabetic patient is a human.

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